HAND SANITIZER WITH IMPROVED DERMAL COMPATIBILITY AND METHOD OF MANUFACTURE

CROSS-REFERENCE TO RELATED APPLICATIONS

This invention claims priority to and the benefit of U.S. Provisional App. Ser. No. 82/422,098 Filed June 5, 2006, the entire contents off which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to hand sanitizer composition and manufacture for improved long term skin health while maintaining antimicrobial efficacy.

BACKGROUND OF THE INVENTION

Hand sanitizer is an alternative to hand washing when hand washing is not feasible or available. Hand sanitizers are effective in decreasing infections in healthcare settings. The active ingredient in hand sanitizer is typically alcohol (1-propanol being most effective followed by 2-propanol and finally by ethanol). Alcohol is bactericidal, tuberculocidal, fungicidal, and virucidal. The highest antimicrobial efficacy can be achieved with ethanol (60% to 85%), isopropanol (60% to 80%), and n-propanol (60% to 80%).

Ethyl alcohol (at concentrations of 60%–80%) inactivates all of the lipophilic viruses, and many hydrophilic viruses. Isopropyl alcohol is not active against the nonlipid enteroviruses, but is fully active against the lipid viruses. The antimicrobial activity of alcohols can be attributed to their ability to denature and coagulate proteins resulting in microbial lysis and disruption of cellular metabolism. To ensure anti-microbial efficacy of alcohol-based hand sanitizers the percentage of alcohol must be less than or equal to 95 wt. %. Hand sanitizer with an alcohol percentage exceeding 95% is less potent because proteins are not denatured easily in the absence of water.

One drawback of alcohol-based hand sanitizers is that they can be drying to skin, and—in more extreme cases—cause contact dermatitis. To counteract alcohol's drying effects humectants and moisturizers are included in alcohol-based hand sanitizers. Too much humectant or moisturizer can leave product build up, and result in stickiness that can make hands feel "dirtier" and impair healthcare workers' ability to place new gloves on their hands.

What is needed is a hand sanitizer and/or method of manufacture of the same that solves one or more the problems described herein.

DETAILED DESCRIPTION

Unless otherwise defined all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs.

The present invention was developed in response to the problems and needs in the art that have not yet been fully solved by currently available hand sanitizers. The present invention has been developed to provide a liquid-based skin sanitizing composition that improves skin health without reducing efficacy of pathogen killing.

Composition

The invention includes a specific ratio of "high" to "medium spreading emollients" (about 3:1 to about 1:3), skin conditioning agents (0.1-1 wt. %), a thickening agent, a linear or branched antimicrobial solution that is made with an alcohol or a mixture of two or more alcohols, and water.

Spreading is measured by the area covered by a fixed amount of oil over a fixed period of time. The preferred method of measurement is used by Cognis and measures mm^2 per 10 minutes. A "high spreading emollient" is one with a spreading value of $>1000mm^2/10$ min. A "medium spreading emollient" is one with a spreading value of $>500mm^2/10$ min and $<1000mm^2/10$ min. An example of a high spreading emollient is 4 10 centisoke silicone oil. An example of a medium spreading emollient is isopropyl myristate. The high spreading emollient should be present at 0-1 wt. %, and the medium spreading emollient should be present in about 0-2 wt. %.

The composition can include at least one skin conditioner that is not less than 0.1 wt. % and not more than 1 wt. % of the final sanitizing composition. An example of a skin conditioner is almond oil.

The amount of water will vary based on the particular form of the composition.

The composition includes a thickener and the amount of thickener will vary based on the desired consistency of the hand sanitizing composition. An example of a thickener is Aristoflex AVC.

Example 1: Components

For a final volume of 1 liter use: 800 mL isopropyl alcohol, 15 mL isopropyl myristate, 5 mL 4 10 centisoke silicone oil, 5 mL aloe vera , 10 g Aristoflex AVC, and 165 mL de-ionized water.

Method of Making Hand Sanitizer Composition

To prepare the hand sanitizer composition, perform the following steps in order: (1) mix the medium spreading oil with the high spreading oil, (2) add desired alcohol to the oil solution and mix, (3) add

desired skin conditioning agent to the solution and mix, (4) homogenize the solution, (5) add the desired thickening agent, and (6) homogenize the solution.

The composition may be provided in various packaging sizes such as 1.5 oz, 500 mL, and 1 L bottles.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments are illustrated by way of example and are not intended to be limited in the accompanying figures.

FIG 1. is a flowchart of a method of manufacturing a hand sanitizer according to one embodiment of the invention.

What is claimed is:

1. A hand sanitizing composition, comprising:

a. a linear or branched antimicrobial solution;
b. a medium spreading emollient;
c. a high spreading emollient;
d. one or more skin conditioners;
e. a thickener; and
f. water;

wherein the weight ratio of said high spreading emollient to said medium spreading emollient is from about 3:1 to about 1:3 and by weight the total emollient mixture comprises no more than 3 wt. % of said sanitizing composition;

wherein the total skin conditioner component comprises no more than 1 wt. % of said sanitizing composition; and

wherein the linear or branched antimicrobial solution is made with alcohol.

2. The hand sanitizing composition of claim **1** wherein said one or more skin conditioners total no more than about 1 wt. % of said composition.

3. The hand sanitizing composition of claim **1** wherein said medium spreading emollient includes one or more of: capric/caprylic triglyceride, C12-15 alkyl benzoate, isopropyl myristate, isopropyl palmitate, octyldodecanol, decyl oleate, cocoglycerides, ethylhexyl stearate, cetearyl isononanoate, cetearyl ethylhexanoate, decyl cocoate, cetyl dimethicone ethylhexyl palmitate, PPG-11 stearyl ether, PPG-15 stearyl ether, 10-20 centisoke dimethicone fluid, and PPG-14 butyl ether.

4. The hand sanitizing composition of claim **1** wherein said high spreading emollient includes one or more of: dicaprylyl carbonate, dibutyl adipate, hexyl laurate, dicaprylyl ether, propylheptyl caprylate, 4 10 centisoke silicone oil, D4, 5, or 6 cyclic siloxane, isocetyl palmitate, hydrogenated polyisobutene, and diethylhexyl carbonate.

5. The hand sanitizing composition of claim **1** wherein said skin conditioner is one or more of the following: alkyl benzoate, myristyl myristate, cetyl myristate, carboxylic acid, glyceryl dioleate, methyl laurate, PPG-9 laurate, lauryl lactate, allantoin, lanolin, propylene glycol, butylene glycol, ethylene glycol, caprylyl glycol, monobutyl ether, glycerine, fatty acids, proline, natural oils such as almond, mineral, canola, sesame, soybean, pyrrolidine, wheat germ, hydrolyzed wheat protein, hydrolyzed oat protein, hydrolyzed collagen, corn, peanut and olive oil, aloe vera, algae extract, gluconic acid, hydrolyzed silk protein, vitamin E, quaternized hydrolyzed protein such as collagen, oat, wheat, inositol, fructose, sucrose, hydrolyzed plant proteins, seaweed extract, glutamic acid, honey, lactose, maltose, sorbitol, shea butter, avocado oils, balm mint oil, cod liver oil, retinol, vegetable oil and mixtures thereof.

6. The hand sanitizing composition of claim **1** wherein said thickener includes one of: cellulosic thickeners and their derivatives, natural gums, starches, stearates, fatty acid, acrylic acid polymers and cross polymers, and Atistoflex AVC.

7. The hand sanitizing composition of claim **1** wherein said composition is in the form of a gel.

8. A method of making a hand sanitizer composition comprising the steps of:

a. mixing together in a vessel a high spreading emollient and a medium spreading emollient in a ratio of from about 3:1 to about 1:3 by weight, wherein the resulting emollient mixture will be about 1 to about 3 wt. % of said final composition;
b. mixing in an antimicrobial solution that will be between about 60 wt. % and about 95 wt. % of said final composition, wherein the antimicrobial solution is made with alcohol;
c. mixing in a skin conditioner with the emollients and antimicrobial solution, wherein the conditioner totals no more than about 1 wt. % of said final composition;
d. homogenizing the mixture of emollient, antimicrobial solution, and skin conditioner;
e. mixing in a thickening agent; and
f. homogenizing the mixture of emollient, antimicrobial solution, skin conditioner, and thickening agent.

9. The method of claim **8** wherein said medium spreading emollient includes one or more of: capric/caprylic triglyceride, C12-15 alkyl benzoate, isopropyl myristate, isopropyl palmitate, octyldodecanol, decyl oleate, cocoglycerides, ethylhexyl stearate, cetearyl isononanoate, cetearyl ethylhexanoate, decyl cocoate, cetyl dimethicone ethylhexyl palmitate, PPG-11 stearyl ether, PPG-15 stearyl ether, 10-20 centisoke dimethicone fluid, and PPG-14 butyl ether.

10. The method of claim **8** wherein said high

spreading emollient includes one or more of: dicaprylyl carbonate, dibutyl adipate, hexyl laurate, dicaprylyl ether, propylheptyl caprylate, 4 10 centisoke silicone oil, D4, 5, or 6 cyclic siloxane, isocetyl palmitate, hydrogenated polyisobutene, and diethylhexyl carbonate.

11. The method of claim **8** wherein said skin conditioner is one or more of the following: alkyl benzoate, myristyl myristate, cetyl myristate, carboxylic acid, glyceryl dioleate, methyl laurate, PPG-9 laurate, lauryl lactate, allantoin, lanolin, propylene glycol, butylene glycol, ethylene glycol, caprylyl glycol, monobutyl ether, glycerine, fatty acids, proline, natural oils such as almond, mineral, canola, sesame, soybean, pyrrolidine, wheat germ, hydrolyzed wheat protein, hydrolyzed oat protein, hydrolyzed collagen, corn, peanut and olive oil, aloe vera, algae extract, gluconic acid, hydrolyzed silk protein, vitamin E, quaternized hydrolyzed protein such as collagen, oat, wheat, inositol, fructose, sucrose, hydrolyzed plant proteins, seaweed extract, glutamic acid, honey, lactose, maltose, sorbitol, shea butter, avocado oils, balm mint oil, cod liver oil, retinol, vegetable oil and mixtures thereof.

12. The method of claim **8** wherein said thickening agent includes one of: cellulosic thickeners and their derivatives, natural gums, starches, stearates, fatty acid, acrylic acid polymers and cross polymers, and Atistoflex AVC.

13. The method of claim **8** wherein said composition is in the form of a gel.

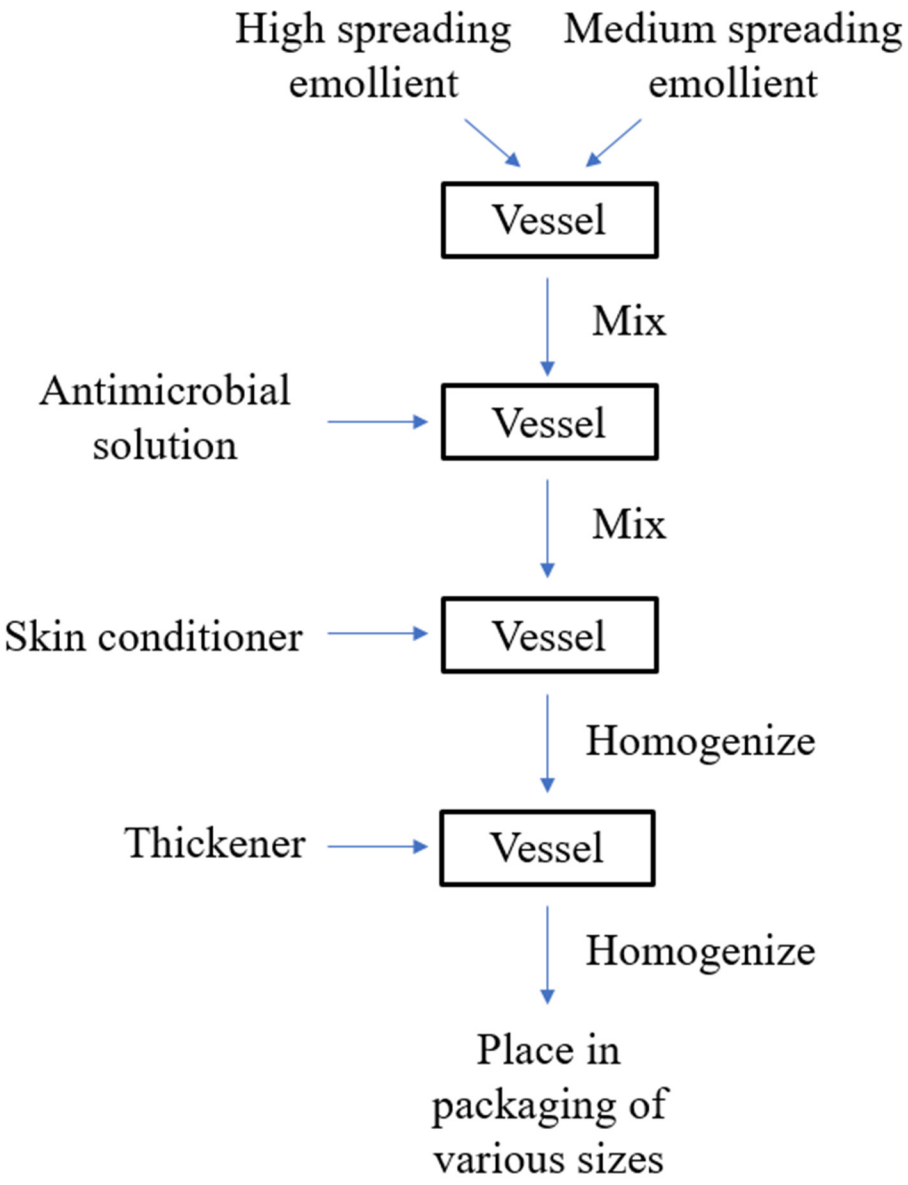
High spreading emollient
Medium spreading emollient
Vessel
Mix
Antimicrobial solution
Vessel
Mix
Skin conditioner
Vessel
Homogenize
Thickener
Vessel
Homogenize
Place in packaging of various sizes

Fig. 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF GILESEAD

GOJI Industries Corp., **Plaintiff,** **v.** **Veejay, Inc.,** **Defendant.**	**Civil Action No. 2020-GSR**

MEMORANDUM ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

This is a patent infringement suit between Plaintiff GOJI Industries Corp. ("Goji") and Defendant Veejay, Inc. ("Veejay"). The patent-in-suit is U.S. Patent No. GSR,835,913 ("the '913 patent"), which is directed to hand sanitizers. This order addresses Veejay's motion for summary judgment of no pre-suit damages.

The pertinent facts are not in dispute: (1) Goji and its licensee produced hand sanitizer using the methods claimed in the '913 patent, (2) neither Goji nor its licensee marked their products with the '913 patent number in accordance with 35 U.S.C. § 287(a), and (3) marking those products was feasible. The question, then, is the legal significance of these facts. Veejay argues that the failure to mark precludes Goji from collecting pre-suit damages. Goji responds that the marking requirement does not apply in cases such as this where only method claims were asserted. In reply, Veejay argues that the marking requirement applies because (1) the patent contains both apparatus

and method claims, and (2) there is a tangible item to mark by which notice of the asserted method claims can be given.

For the reasons discussed below, I grant Veejay's motion for summary judgment on the issue of pre-suit damages.

I. LEGAL STANDARDS

Summary judgment is proper if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).

35 U.S.C. § 287(a) bars a patentee from collecting damages for any infringement that occurred before the infringer had notice of the patent. *See* 35 U.S.C. § 287(a). "The statute permits either constructive notice, which is accomplished by marking the article with the patent number, or actual notice." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1345 (Fed. Cir. 2001). Patent marking can be accomplished in two ways: (1) by physically marking a product with a patent number, or (2) by "fixing [on the product] the word 'patent' or the abbreviation 'pat.' together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent." 35 U.S.C. § 287(a).

The two Federal Circuit cases that most directly address the issue of when marking is required are in tension. On one hand, the Federal Circuit has held that "the marking requirement of 35 U.S.C. § 287(a) does not apply" if the patentee has asserted method claims only. *Crown Packaging Tech., Inc. v. Rexam Bev. Can Co.*, 559 F.3d 1308, 1316-17 (Fed. Cir. 2009). In an earlier case, however, the Federal Circuit held that "[w]here the patent contains both apparatus and method claims [and] there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to avail itself of the constructive notice

provisions of section 287(a)." *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.4d 1523, 1538-39 (Fed. Cir. 1993). *Crown Packaging* did not purport to abrogate *American Medical*.

II. DISCUSSION

The central question before the Court is whether the marking requirement applies in this case. Veejay argues that it does, citing *American Medical*; Goji argues that it does not, citing *Crown Packaging*.

The patent-in-suit in *Crown Packaging* was U.S. Patent No. 4,774,839 ("the '839 patent"). 559 F.3d at 1310. The '839 patent was directed to "[a] die necking method and apparatus for producing a smooth tapered wall between the container side wall and a reduced diameter neck." '839 patent, Abstract.[1] The '839 patent included both apparatus claims and method claims. *See id.*, claims 1-43. The apparatus claims recited a "[n]ecking apparatus," and the method claims recited a method of using that apparatus. *See id.* In the litigation, however, the patentee asserted only the method claims. *Crown Packaging*, 559 F.3d at 1316. The district court granted the accused infringer's summary judgment motion to dismiss the claims against it due to the patentee's failure to mark. *Id.* at 1315-16. The Federal Circuit reversed "[b]ecause Rexam asserted only the method claims of the 839 patent, [and] the marking requirement of 35 U.S.C. § 287(a) does not apply" when only method claims are asserted by the patentee. *Id.* at 1315-17.

In *American Medical*, the patent-in-suit claimed "an apparatus and method for packaging a fluid-containing penile prosthesis in a pre-filled, sterile state." *Am. Med.*, 6 F.3d at 1527. The patentee asserted both the method and apparatus claims. *Id.* at 1539. The district court held that the patentee was not entitled to pre-suit damages because they sold unmarked products practicing

[1] Descriptions of the '839 patent are not factual findings by the Court. The description of the '839 patent is provided solely by way of background.

the patent-in-suit. The Federal Circuit affirmed because "both apparatus and method claims of the '765 patent were asserted and there was a physical device produced by the claimed method that was capable of being marked." *Id.* The court added: "to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to avail itself of the constructive notice provisions of section 287(a)." *Id.* at 1538-39.

The holding of *American Medical* applies most directly to the facts before the Court. It is undisputed that (1) the '913 patent contains both method and apparatus claims; and (2) there was a tangible item to mark, *i.e.*, Goji's hand sanitizer product, by which constructive notice of the asserted method claims could have been given. *Crown Packaging* is distinguishable in that the asserted claims in that case recited methods of using an apparatus. Here, the asserted claims recite methods of *making* a product. The Court finds this difference to be significant. Method-of-using claims do not necessarily yield a tangible item that can be marked, whereas method-of-making claims do. *Crown Packaging* also fails to specifically address instances where there are both method claims and an item to mark.

To the extent there is a conflict between *American Medical* and *Crown Packaging*, the former must control. *See Tex. Instruments, Inc. v. United States ITC*, 846 F.2d 1369, 1372-73 (Fed. Cir. 1988) ("A panel decision cannot overturn any precedential ruling of the court, even of a prior panel, much less that of an [e]n banc court."); *see also Deckers Corp. v. United States*, 752 F.3d 949, 959 (Fed. Cir. 2014) ("In this Circuit, a later panel is bound by the determinations of a prior panel, unless relieved of that obligation by an en banc order of the court or a decision of the Supreme Court.").

Finally, applying *Crown Packaging* here would frustrate the policy objectives of the marking requirement. The purposes of the marking requirement are threefold: "(1) helping to avoid

innocent infringement; (2) encouraging patentees to give public notice that the article is patented; and (3) aiding the public to identify whether an article is patented." *Arctic Cat Inc. v. Bombardier Rec. Prods.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017) (quoting *Nike Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1443 (Fed. Cir. 1998)). The marking statute drives towards those ends by providing patentees a financial incentive to mark their products—by marking, a patentee gains the right to seek pre-suit damages. If I were to extend *Crown Packaging* to this case, however, I would effectively be gifting Goji the right to pre-suit damages without advancing any of the goals of the marking requirement.

It is undisputed that Plaintiff failed to mark although marking was feasible. This fact is dispositive for the Court's ruling.

III. CONCLUSION

For the foregoing reasons, the Court holds that the marking requirement applies in this case, and Goji is not entitled to pre-suit damages because it failed to satisfy that requirement. Veejay's Motion for Summary Judgment is hereby **GRANTED**.

Dated: December 18, 2020

/s/ Anthony Bryant
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF GILESEAD

GOJI Industries Corp.,	)	
	)	
Plaintiff	)	
	)	Civil Action No. 2020-GSR
v.	)	
Veejay, Inc.,	)	
	)	
Defendant.	)	

January 19, 2021
ALL PARTICIPANTS APPEARING VIA WHOOSH

BEFORE: THE HONORABLE ANTHONY BRYANT
United States District Judge

APPEARANCES:

SMITH & SMITH LLP
BY: JAMES SPLIT

Counsel for the Plaintiff

JONES & JONES LLP
BY: ABIGAIL FOREST

Counsel for the Defendant

REPORTED BY: ANNE REISCHL, CRR, RPR
COURT REPORTER FOR THE DISTRICT OF GILESEAD

*** LINES OMITTED ***

CAROLINA SCOTT, a witness produced on call of the Plaintiff, having been duly sworn according to law, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. SPLIT:

***Q*:** Good morning Dr. Scott, can you state your full name for the record?

***A*:** Carolina H. Scott.

Q: What is your professional background?

A: I have a Ph.D. in microbiology, and I have 20 years of experience as a sterile manufacturing consultant. I help manufacturers who need to optimize their sterile manufacturing practices.

Q: What does that entail?

A: I inspect plants to ensure they follow best practices for aseptic production. This requires me to be very familiar with each step of the manufacturing process to ensure there is no contamination at any point of production. I also need to know what is in the end product to help companies develop a production method that ensures sterility from start to finish, without compromising the product's quality.

Q: Have you ever consulted or worked for either of the parties in this case?

A: No. I mean, I was hired by Goji as an expert witness in this case, but I have not done any work for either party outside the context of this litigation.

Q: And you have not worked in a plant manufacturing either party's products?

A: No.

*** LINES OMITTED ***

Q: How about the term "made with alcohol"? In your professional opinion, does Veejay practice this term in their manufacture of VireX?

A: Yes.

Q: Why do you say that?

A: Again, as with the other claim limitations, I looked at Veejay's internal documents that explain how they make VireX. And if you go to page 43 of this exhibit—

Q: Jeremy, can we please put up page 43 of Exhibit 12? Great, thanks.

A: Right, so as you can clearly see here, Veejay uses alcohol as an ingredient in VireX, specifically to make the product's antimicrobial solution.

*** LINES OMITTED ***

Q: Dr. Scott, based on all the evidence you examined, do you have an opinion as to whether Veejay infringes the asserted claims of Goji's patent?

A: Yes, I would say definitely.

Q: Thank you, Dr. Scott. No further questions.

CROSS-EXAMINATION

BY MS. FOREST:

*** LINES OMITTED ***

Q: The claims also require that the antimicrobial solution of the hand sanitizer is "made with alcohol." Do you see that?

A: Yes.

Q: What does that mean to you?

A: I think it's pretty self-explanatory – alcohol is used in the process of making the antimicrobial solution.

Q: What are you basing your opinion on?

A: It's not really an opinion, it's just English. The claim says "made with alcohol," and that just means alcohol is used somewhere in the process.

Q: Where in the '913 patent does it say that?

A: I don't think it does, but it doesn't need to. Again, I'm just reading the words of the claims.

Q: You testified earlier that VireX is made with alcohol, right?

A: Yes.

Q: Why do you say that?

A: As I explained, I inspected Veejay's technical specifications, and they show that Veejay uses alcohol as a reagent.

Q: What does that mean?

A: It means that alcohol is an ingredient in the process – they add alcohol to the mixture to create a reaction.

Q: But isn't it true that the finished product doesn't contain alcohol?

A: Yes, that's true, but that's not what the claim requires. The claim just says "made with alcohol," and as I said before, Veejay's specifications show that their process uses alcohol as a reagent.

Q: Let's suppose, for argument's sake, that "made with alcohol" means the end product must contain alcohol. Under that reading, wouldn't you agree that Veejay doesn't practice the "made with alcohol" limitation?

A: Maybe.

Q: Well it does or it doesn't, Dr. Scott, and I believe you just testified that the finished product doesn't contain alcohol. Isn't that what you said?

A: I did say that, but whether the finished product contains alcohol or not doesn't matter. That's not what the claim requires.

Q: I understand that's your position. But what if you're wrong, and "made with alcohol" does require that the finished product contains alcohol?

A: Yes, in that case, Veejay would not practice the "made without alcohol" limitation.

Q: Thank you, Dr. Scott. I have no further questions.

*** LINES OMITTED ***

SARAH WELLEN, a witness produced on call of the Defendant, having been duly sworn according to law, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. FOREST:

Q: Good afternoon Dr. Wellen, can you state your full name for the record?

A: My name is Sarah J. Wellen.

Q: What are your professional qualifications?

A: I have a Ph.D. in chemical engineering, and I've spent 30 years ensuring companies are FDA-compliant when producing their products. Many of the companies I work with produce hand sanitizer. I have to be familiar with the formulations and production methods at all of these plants to ensure they follow FDA's Current Good Manufacturing Practices regulations.

Q: So, you would say you are very familiar with a variety of hand sanitizer formulations and methods of production?

A: Yes, I would say so.

Q: Have you worked — in any capacity — for either of the parties in this suit?

A: No, I have not.

*** LINES OMITTED ***

Q: I'd like to ask you about the claim limitation that requires the antimicrobial solution of the hand sanitizer be "made with alcohol." Do you have an opinion as to whether Veejay's manufacturing process satisfies that requirement?

A: Yes, I do.

Q: And what is your opinion?

A: It seems fairly obvious that Veejay's manufacturing process does not satisfy that requirement.

Q: What makes you say that?

A: There is simply no alcohol—not even a trace—in the end product. Veejay's end product uses an entirely different antimicrobial solution. Specifically, it uses benzalkonium chloride instead of alcohol.

Q: And when you say "end product," what are you referring to?

A: VireX.

Q: Earlier today, you heard Dr. Scott testify that Veejay's manufacturing process does satisfy the "made with alcohol" requirement. Can you explain why your opinion differs from Dr. Scott's?

A: Sure. I believe Dr. Scott is assuming that the "made with alcohol" requirement can be satisfied by the mere use of alcohol at some point in the manufacturing process. But that does not make sense. The plain meaning of the phrase "made with alcohol" is that the end product contains alcohol. I would never say something is "made with WD-40" just because we use it to lubricate machine parts. A product is "made with" the ingredients that actually go into the product.

Q: Based on all of the evidence you've been shown, do you think there was any infringement here by Veejay?

A: No, absolutely not.

Q: Thank you, Dr. Wellen. Nothing further.

CROSS-EXAMINATION

BY MR. SPLIT:

*** LINES OMITTED ***

Q: Let's talk about the term "made with alcohol." What do you interpret that term to mean?

A: That the end product contains alcohol.

Q: Couldn't another interpretation be that alcohol is used somewhere in the manufacturing process?

A: No, I don't think so. As I said before, that just wouldn't make sense.

Q: You testified earlier that the plain meaning of "made with alcohol" is that the end product contains alcohol. What are you basing that on?

A: Well the full claim term says "wherein the antimicrobial solution is made with alcohol." It doesn't say "wherein the method includes using alcohol."

Q: What if the claim required that "the antimicrobial solution is made with WD-40"? You said earlier that Veejay wouldn't practice that theoretical limitation if all it did was use WD-40 to lubricate its machine parts—

A: That's not what I said.

Q: I believe you testified that you would "never say something is made with WD-40 just because we use it to lubricate machine parts." Wasn't that your testimony?

A: Yes, I think that's correct.

Q: Ok so if the claim said "wherein the antimicrobial solution is made with WD-40," would it be your opinion that Veejay does not practice that term even if it uses WD-40 to lubricate its machine parts?

A: That's a hypothetical question—

Q: Well, it's your hypothetical, Dr. Wellen. You brought up WD-40. So are you going to answer my question or not?

A: What is the question again?

Q: If the claim said "wherein the antimicrobial solution is made with WD-40," and Veejay used WD-40 only to lubricate its machine parts, would it be your opinion that Veejay doesn't practice that limitation?

A: Yes.

Q: Thank you. I believe you also testified that "a product is made with the ingredients that actually go into the product." Is that your testimony?

A: That's correct.

Q: Isn't it true that Veejay uses alcohol as an ingredient to make VireX?

A: No, I don't believe so.

Q: Why not?

A: There's no alcohol in the finished product, so alcohol is not an ingredient.

Q: But doesn't Veejay use – doesn't it add alcohol to the mixture during the manufacturing process?

A: Yes, but the alcohol is entirely consumed in the process. There's not even a trace of alcohol in the finished product.

Q: I understand the alcohol is consumed in the process, but isn't it still an ingredient?

A: I guess that depends on your interpretation of "ingredient." I think of alcohol in this context as more of a reactant – a reagent, if you will. But it's not an ingredient in the finished product.

Q: So, in your opinion, a reagent is not an ingredient.

A: No, not necessarily.

Q: Do you cook, Dr. Wellen?

A: Yes, of course.

Q: Have you ever cooked with wine?

A: Yes, and sometimes I even put it in the food.

Q: And when you're cooking with wine, wouldn't you say that wine is an ingredient?

A: I suppose so.

Q: And wine includes alcohol, correct?

A: Obviously.

Q: So then alcohol is an ingredient when you cook with wine.

A: Sure.

Q: Even if the alcohol is cooked off?

A: I see your point, but cooking is different from chemistry. A cook might say that alcohol is an ingredient in a dish even if the alcohol gets cooked off. But a chemist talking about a chemical process would not say that alcohol is an ingredient if it is merely used as a reactant.

Q: What are you basing that on?

A: Just my experience, I guess. I have a Ph.D. in chemical engineering, and I've worked in industry for 30 years. I know how chemists talk and refer to things.

Q: So in your professional opinion, Veejay does not practice the "made with alcohol" limitation of the claims even though alcohol is used as a reagent, that's your testimony?

A: That's correct.

Q: And just so I'm understanding your testimony correctly, you're basing your opinion on the assumption that the "made with alcohol" limitation requires there to be alcohol in the finished product, right?

A: I wouldn't really call it an assumption. I read "made with alcohol" to mean that there is alcohol in the finished product, as would any experienced chemist. In fact, I reviewed some emails between the named inventors of the asserted patent, and they themselves said that Veejay does not practice this limitation if the end product is devoid of alcohol, which it is.

Q: Just to be clear, though, it doesn't say that in the patent, correct?

A: That's correct. The patent doesn't explain what "made with alcohol" means.

Q: And the emails you're referring to were recent, many years after the inventors filed their patent application, right?

A: Yes, that's true.

Q: Thank you, Dr. Wellen. That will be all.

Meet up next week?

4 messages

Greg Lawson < glaws@goji.com> Jan 10, 2020 at 8:14 AM
To: Andrea Brodsky <abrodsky@goji.com>

Hey Andy,

I hope you are well. We should grab a beer sometime next week. I want to pick your brain about a new anti-microbial we should consider using.

I also wanted to flag something for you. Have you heard about Veejay's new product, VireX? Tony told me they're making the stuff using a process similar to the one we invented. Not sure where he's getting his intel, but maybe we should ask legal to investigate?

Best,
Greg

--
Greg Lawson, Ph.D.
Principal Scientist
GOJI Industries Corp.
glaws@goji.com
(760) 562-244

Andrea Brodsky <abrodsky@goji.com > Jan 10, 2020 at 9:00 AM
To: Greg Lawson < glaws@goji.com>

Hi Greg,

Yes. Let's plan on Wednesday next week. I have a presentation on Tuesday, so I am going to be MIA while prepping.

Hmmmmm. Thanks for letting me know. I don't really know if there is an issue here. I quickly took a look at Veejay's website, and it says their hand sanitizer contains no alcohol. If we are thinking about the same Tony then he's more of a sales guy and might not know much about Veejay's products. Still, it can't hurt to ask legal to explore. We can also buy some of Veejay's product and test whether or not it contains alcohol. They can say anything they want on their website, but that doesn't mean it's true.

Andy
[Quoted text hidden]

--
Andrea Brodsky, M.D., Ph.D.
Principal Scientist
GOJI Industries Corp.
abrodsky@goji.com

Greg Lawson < glaws@goji.com> Jan 10, 2020 at 9:30 AM
To: Andrea Brodsky <abrodsky@goji.com >

I can't do Wednesday, maybe Friday?

I think we are talking about the same Tony (Tony Keller) who is in sales. But regarding the product that's a fair point. I should have checked it out before getting worried. If it doesn't have any alcohol in it then there likely isn't a problem.

But to be safe I think you should definitely reach out to legal. It would be a bummer if we run into issues down the road that we could have avoided by getting the lawyers involved. I would email Marie first. She has been super helpful before, and we might want to check-in with her before we get more people involved.

G
[Quoted text hidden]

--
Greg Lawson, Ph.D.
Principal Scientist
GOJI Industries Corp.
glaws@goji.com
(760) 562-244

Andrea Brodsky <abrodsky@goji.com > Jan 10, 2020 at 10:00 AM
To: Greg Lawson < glaws@goji.com>

Ya, Friday is good. Do you want to go to the place down the block? They have a pretty good selection of stouts—your fave.

Like I said; I wouldn't worry that much about Veejay. I don't think there is an issue. I will email Marie though and cc you. I'm going to start a new email thread though—I have a meeting in 15 so look out for the email this afternoon. If you don't see anything by 5 today can you remind me—just in case I forget.

Andy
[Quoted text hidden]

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Andrea Brodsky, M.D., Ph.D.
Principal Scientist
GOJI Industries Corp.
abrodsky@goji.com

Greg Lawson < glaws@goji.com> Jan 10, 2020 at 10:15 AM
To: Andrea Brodsky <abrodsky@goji.com >

Will Do!
[Quoted text hidden]

--
Greg Lawson, Ph.D.
Principal Scientist
GOJI Industries Corp.
glaws@goji.com
(760) 562-244

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF GILESEAD

GOJI Industries Corp., **Plaintiff,** **v.** **Veejay, Inc.,** **Defendant.**	**Civil Action No. 2020-GSR**

MEMORANDUM ORDER DENYING PLAINTIFF'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

Before the Court is Plaintiff Goji's renewed motion for judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50(b). Defendant Veejay opposes the motion. For the reasons set forth below, Goji's motion will be DENIED.

I. BACKGROUND

In April 2020, Goji filed a complaint accusing Veejay of infringing U.S. Patent No. GSR,835,913 ("the '913 patent"). The '913 patent is directed to a hand sanitizer and methods for making the same. Goji asserts claim 8 and its dependents, all of which are method claims. Claim 8 recites:

8. A method of making a hand sanitizer composition comprising the steps of:

a. mixing together in a vessel a high spreading emollient and a medium spreading emollient in a ratio of from about 3:1 to about 1:3 by weight, wherein the resulting emollient mixture will be about 1 to about 3 wt. % of said final composition;

b. mixing in an antimicrobial solution that will be between about 60 wt. % and about 95 wt. % of said final composition, wherein the antimicrobial solution is made with alcohol;

c. mixing in a skin conditioner with the emollients and antimicrobial solution, wherein the conditioner totals no more than about 1 wt. % of said final composition;

d. homogenizing the mixture of emollient, antimicrobial solution, and skin conditioner;

e. mixing in a thickening agent; and

f. homogenizing the mixture of emollient, antimicrobial solution, skin conditioner, and thickening agent.

The accused process is Veejay's manufacture of its VireX hand sanitizer. VireX is dissimilar from other popular hand sanitizers in that it uses benzalkonium chloride rather than alcohol to kill germs. Veejay's manufacturing process does, however, employ alcohol as a reagent that is entirely consumed in the process. Because of the COVID-19 pandemic, demand for VireX has soared.

Before trial, Goji moved for summary judgment of infringement under Federal Rule of Civil Procedure 56, arguing there was no dispute that Veejay practices every limitation of the asserted claims in its manufacture of VireX. For support, Goji cited Veejay's technical documents showing how VireX is manufactured. In response, Veejay argued that summary judgment of infringement would be improper because the parties had a genuine dispute of material fact as to whether VireX's antimicrobial solution (benzalkonium chloride) is "made with alcohol," as claim 8 requires. Goji replied that the dispute over the "made with alcohol" limitation was purely a claim construction issue for the court to decide as a matter of law. The Court denied Goji's motion for summary judgment and declined to construe "made with alcohol" because Goji had not shown "a fundamental dispute regarding the scope of [this] claim term." *O2 Micro Int'l v. Beyond Innovation Technology Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

In January 2021, the Court held a five-day jury trial remotely over Whoosh. At trial, Veejay's sole non-infringement argument was that it does not practice the "made with alcohol" limitation of claim 8 because VireX does not contain any alcohol. Veejay did not dispute that it

practices every other limitation of the asserted claims, nor did it dispute that it uses alcohol as a reagent in manufacturing VireX. Before jury deliberations, Goji moved for judgment as a matter of law that Veejay infringes the '913 patent under a proper construction of "made with alcohol." The Court denied Goji's motion for the same reasons it denied Goji's motion for summary judgment. The jury returned a verdict of non-infringement of all asserted claims. Goji then filed the present motion.

II. LEGAL STANDARD

"The standard for granting a Rule 50 motion is stringent." *Malone v. Lockheed Martin Corp.*, 610 F.3d 16, 20 (1st Cir. 2010). In making its determination, the Court must view "'[a]ll of the evidence and reasonable inferences drawn from the evidence … in the light most favorable to' the non-moving party." *Id.* (quoting *Espada v. Lugo*, 312 F.3d 1, 2 (1st Cir. 2002)). The Court may not weigh the evidence, determine the credibility of the witnesses presented, or attempt to resolve conflicting testimony. *MacQuarrie v. Howard Johnson Co.*, 877 F.2d 126, 128 (1st Cir. 1989). The Court may enter judgment as a matter of law "only if the evidence, viewed from this perspective, 'would not permit a reasonable jury to find in favor of the [non-movant] on any permissible claim or theory.'" *Andrade v. Jamestown Housing Authority*, 82 F.3d 1179, 1186 (1st Cir. 1996) (quoting *Murray v. Ross-Dove Co.*, 5 F.3d 573, 576 (1st Cir. 1993)); *see also Malone*, 610 F.3d at 20 ("Courts may only grant a judgment contravening a jury's determination when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party." (internal quotation marks omitted)).

III. DISCUSSION

Goji urges the Court to disregard the jury's verdict of noninfringement and hold as a matter of law that Veejay's manufacturing process infringes the method claims of the '913 patent. Veejay responds that the jury's finding of noninfringement is supported by evidence that the end product is completely free of alcohol and therefore does not satisfy the "made with alcohol" limitation of claim 8. Goji replies that Veejay's argument reveals a fundamental dispute as to the scope of the claims and thus requires the Court to construe the "made with alcohol" term.

"Words of a claim are generally given their ordinary and customary meaning." *O2 Micro*, 521 F.3d at 1360. "[A] district court is not obligated to construe terms with ordinary meanings." *Id.* However, "[w]hen the parties raise an actual dispute regarding the proper scope of the[] claims, the court, not the jury, must resolve that dispute." *Id.* "A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." *Id.* at 1361. For example, if "the parties dispute[] not the *meaning* of the words themselves, but the *scope* that should be encompassed by th[e] claim language," then a determination that the term "needs no construction" might not "resolve the parties' dispute." *Id.*

Here, it is not necessary for the Court to construe the "made with alcohol" limitation because Goji and Veejay merely dispute the meaning of its words, not its scope. Goji posits, through its expert witness, that "made with alcohol" means the process "alcohol is used in the process." Veejay retorts, through its own expert witness, that "made with alcohol" means "the end product contains alcohol." Each expert insists that her interpretation reflects the plain

meaning of the claim language. *See* Trial Tr. at 3:19-30 ("I'm just reading the words of the claims."); *id.* at 6:6-14 ("The plain meaning of the phrase 'made with alcohol' is that the end product contains alcohol."). Yet neither party has presented pertinent evidence, either intrinsic or extrinsic, supporting its expert's *ipse dixit*.[1] The Court also notes that the specification of the '913 patent is not helpful because it merely repeats the limitation without providing any clarification as to its meaning. The parties' dispute thus boils down to mere attorney argument over "the *meaning* of the words ['made' and 'with'] themselves," with neither side presenting compelling evidence as to "the *scope* that should be encompassed by this claim language." *O2 Micro*, 521 F.3d at 1361 (emphasis in original). Accordingly, it was within the jury's province to resolve that dispute.

With that in mind, the Court holds that a reasonable jury could find Veejay's manufacture of VireX noninfringing because the end product does not contain any alcohol and is therefore not "made with alcohol," as all asserted claims of the '913 patent require.

IV. CONCLUSION

For the foregoing reasons, Goji's renewed motion for judgment as a matter of law is DENIED. Final judgment consistent with this opinion shall enter pursuant to Federal Rule of Civil Procedure 58.

Dated: February 4, 2021

/s/ Anthony Bryant
UNITED STATES DISTRICT JUDGE

[1] Veejay does cite internal emails between the named inventors of the '913 patent showing their belief that "made with alcohol" means the end product contains alcohol. Such evidence is, however, irrelevant. *Howmedica Osteonics Corp. v. Wright Medical Technology, Inc.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008) ("[I]nventor testimony as to the inventor's subjective intent is irrelevant to the issue of claim construction.").